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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,354	01/17/2006	Martin Beer	DEBE:049US/10501329	8965

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EXAMINER	
MOSHER, MARY	
ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
05/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,354	BEER ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18/18/07, 2/13/08*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 11-13* is/are pending in the application.

4a) Of the above claim(s) *1-8,11 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/22/06, 8/31/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group II, species herpesvirus in the reply filed on 2/13/2008 is acknowledged. Claims 1-8, 11 and 12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/13/2008.

Claim Objections

Applicant is advised that should claim 9 be found allowable, claim 13 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The claims are identical, as amended.

Claim Rejections - 35 USC § 112

Claims 9 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are very confusing, for several reasons. It is not clear what is meant by "a derived from a virus" or "a virus which naturally not uses humans or other animal species as a host or dead-end host." If a virus does not use humans or animals as a host, and if humans or other animals are

not dead-end hosts, what other choices are there? There are no herpesviruses that infect plants or bacteria.

It is also unclear what is meant by "naturally." For example, mice are not the natural host for equine herpesvirus 1 (EHV1) , but mice can be infected with EHV1 and the virus is pathogenic in mice, see for example Neubauer et al (cited in IDS). So would treatment of mice with recombinant EHV-1 be included or excluded from the scope of the claims?

Also, the claims required an ability to transduce in vitro primary cells of an organism which is not a natural or dead-end host with a multiplicity of less than one. However, there are many types of primary cells, with differing abilities to be transduced; if the virus efficiently infects primary liver cells but not PBMC, is it included or excluded from the claim? Also, the recitation "less than 10^6 to 10^8" is confusing; does it mean less than 10^6, less than 10^8, or in the range between 10^6 - 10^8? Also, the claims lack antecedent basis for "said recombinant animal virus."

Claims 9 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection. This rejection involves possession of "a virus" with specific functional characteristics. The claims clearly encompass a genus of viruses, those viruses which are capable of transducing primary cells of a nonpermissive host at a mutliplicity of infection of less

than 1 (MOI<1). The specification does not teach any specific features of viruses which give them the required ability. The specification reduces to practice one species of virus with the required capability, Equine herpesvirus type 1 (EHV1), and teaches that a related species of herpesvirus (bovine herpesvirus 1, BHV1) lacks the required capability. Therefore, the required ability is unpredictable. The state of the art does not indicate widespread knowledge of viruses able to transduce nonpermissive host cells at MOI<1. Therefore, considering the broad scope of the genus, the absence of general teachings in the specification, the unpredictability of the art, and the reduction to practice of only a single species, it is concluded that the specification does not reasonably convey that applicants possessed the full scope of the claimed genus of viruses.

Claims 9 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection has two aspects: “a virus” with specific functional characteristics, and “treating or preventing a disease”

First, "a virus." As discussed above, this part of the claim involves a broad genus of viruses, which are defined functionally by their ability to transduce primary cells of an abnormal host at MOI<1. The specification does not teach any specific features of viruses which give them the required ability. The specification teaches that the ability is unpredictable, since EHV1 has the ability but BHV1 does not. The working examples of

viruses with the required function are limited to EHV1. Considering the broad scope of the claim, the limited teachings of the specification, the unpredictability of the art, the state of the art, and the limited scope of the working examples, it is concluded that undue experimentation would be required to discover and use viruses other than EHV-1 that meet the functional requirements of the claims.

Second, "treating or preventing a disease." The specification teaches that EHV-1 can infect PBMCs from several non-equine species of animal, including humans, and that EHV-1 can express green fluorescent protein in lungs and airway tissue of mice. However, infection and expression is not necessarily sufficient to treat or prevent a disease. If the disease is one of a gene deficiency, the vector must express the product in sufficient quantity in the appropriate location in order to achieve the desired therapeutic benefit. If the disease is one that is treated or prevented by an immune response, again the vector must express the product in sufficient quantity in an appropriate location in order to achieve the desired immune response. Applicant has provided no evidence that expression from EHV-1 in an abnormal host is sufficient to achieve the required therapeutic benefit. Considering the broad scope of the claims, the limited teachings in the specification, the absence of a working example of treating or preventing a disease, the state of the art, and the unpredictability of therapy, it is concluded that undue experimentation would be required to enable the invention as claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Neubauer et al (cited in IDS). Mice are not naturally the host of EHV-1. Neubauer teaches administration of 1 x 10^5 pfu of recombinant EHV-1 to mice, see page 37. This prevented disease in the mice when they were challenged with virulent EHV, see Figure 4. Although the reference is silent upon the ability of the recombinant EHV-1 to transduce primary cells at low MOI, this would necessarily be an inherent characteristic of the recombinant EHV. Therefore, the reference meets each and every limitation of the invention as claimed.

The following references are cited as illustrating the state of the art:

Donofrio et al, "Potential of bovine herpes 4 as a gene delivery vector", Journal of Virological Methods 101:49-61, 2002.

Markham et al WO 98/37905, for teaching the ability of EHV-1 to infect human cells and explicitly suggesting administration of the virus to humans for gene therapy and cancer treatment.

Phillips, "The challenge of gene therapy and DNA delivery," Journal of Pharmacy and Pharmacology 53: 1169-1174, 2001, for illustrating the state of the art for gene therapy.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on varying dates and times; please leave a message.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher, Ph.D./
Primary Examiner, Art Unit 1648

4/30/08